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PUBOVAGINAL SLING USING ALLOGRAFT FASCIA LATA VERSUS AUTOGRAFT FASCIA FOR ALL TYPES OF STRESS URINARY INCONTINENCE: 2-YEAR MINIMUM FOLLOWUP

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ABSTRACT

Purpose: Allografts have been substituted for autografts as a pubovaginal sling to decrease postoperative morbidity, although to our knowledge their long-term durability is unknown. Since 1997, we have offered allograft fascia lata as an alternative to autograft fascia in women undergoing the pubovaginal sling procedure. We describe our continued experience with those with a minimum 2-year followup.

Materials and Methods: We retrospectively reviewed the records of 134 consecutive women with all types of stress urinary incontinence but without neurovesical voiding dysfunction or a significant degree of pelvic prolapse who underwent pubovaginal sling (allografts in 63 and autografts in 71) performed by a single surgeon. Rectus abdominis or fascia lata autograft and freeze-dried, γ irradiated allograft slings were placed using identical techniques and a 2×12 cm. piece of fascia. Outcome analysis included a chart review, third party telephone interview and selective videourodynamics. Surgical outcome was categorized by daily pad use as cured—0, improved—1 or failed—greater than 1 pad.

Results: Of 140 women who received a pubovaginal sling 134 were still evaluable. Preoperative parameters were similar in each group. Mean followup plus or minus standard deviation was less in the allograft group (29 ± 3 versus 44 ± 7 months, $p < 0.05$). There was no statistical difference in the overall stress and urge incontinence cure rate in the allograft and autograft groups (45 of 63 cases and 55 of 71, $p = 0.42$), nor was there a difference in the total number with recurrent stress urinary incontinence (8 and 7, respectively, $p = 0.58$). In 24% and 16% of cases postoperative incontinence was due to urge incontinence in the allograft and autograft groups, respectively. Using allografts instead of autografts resulted in a significantly decreased postoperative pain and disability ($p < 0.05$).

Conclusions: Using allograft fascia lata as an alternative to autologous fascia for a pubovaginal sling significantly decreases postoperative pain and disability without compromising efficacy at 2 years. Therefore, we believe that allograft fascia should remain a suitable alternative to autografts for pubovaginal slings.

KEY WORDS: bladder; urinary incontinence, stress; transplantation, homologous; fascia lata

The pubovaginal sling is recognized as effective treatment for stress urinary incontinence.[1] Before gaining this recognition it has undergone considerable modifications since 1907, when it was initially described.[2] Initially autologous gracilis or pyramidalis muscle was used to treat urinary incontinence.[2] In 1914 Frangenheim modified the Goebell procedure using a composite autograft of pyramidalis or rectus abdominis muscle with overlying fascia.[2] In 1942 Aldridge noted that the previous success of the Goebell procedure was achieved by improved suburethral support and not by a "sphincterlike action of contracting muscle," and so used hinged rectus fascia without a muscular backing to support the urethra.[2] Although the pubovaginal sling of autologous fascia effectively cured stress urinary incontinence, it fell out of favor due its complexity and associated morbidity.[3]

The pubovaginal sling was reintroduced with modifications in 1978 by McGuire and Lytton, who used a hinged rectus fascial sling to achieve continence in 80% of patients with intrinsic sphincter deficiency.[4] In 1991 Blaivas and Jacobs modified the procedure further by using unattached rectus fascia, which decreased the tendency for sling over tightening, which may result in urinary retention or detrusor instability.[3] Recently the autograft pubovaginal sling has been used effectively as a primary treatment for stress urinary incontinence due to urethral hypermobility.[5,6] This expanded use is supported by the premise that all patients with stress urinary incontinence have some degree of intrinsic sphincter deficiency and would benefit from suburethral support.[7]

The choice of sling material continues to evolve as investigators seek the ideal material that would obviate the need for fascial harvest, thereby, decreasing forever the morbidity and complexity of the procedure without compromising efficacy and safety. Our preliminary report and those of others show decreased postoperative morbidity when using allograft fascia, which did not occur at the expense of efficacy or safety at less than 1 year.[8–10] However, there are also reports of early sling failure due to allograft autolysis.[11,12] This disagreement prompted us to review our continued experience with the same cohort of women with a minimum 2-year followup.

MATERIALS AND METHODS

We performed a retrospective continued review of consecutive women who received an allograft or autograft pubovaginal sling for all types of stress urinary incontinence from December 1995 to August 1998. All procedures were done at

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our institution by a single surgeon (W. T. Y.). Patients with incontinence due to neurovesical dysfunction or those with concomitant pelvic surgery were excluded from analysis.

Preoperative evaluation included a voiding history, urogynecologic examination, urinalysis and single channel cystometrography with abdominal leak point pressure. Indications for detailed videourodynamics were stress urinary incontinence not readily demonstrable, previous anti-incontinence surgery, obstructive voiding symptoms and moderate to severe pelvic prolapse. Types II, III (intrinsic sphincter deficiency) and II-III stress urinary incontinence were defined as bladder neck hypermobility with abdominal leak point pressure greater than 90 cm. water, and abdominal leak point pressure less than 60 and 61 to 90 cm. water, respectively.

From December 1995 to August 1997 only autografts were available for patients undergoing the pubovaginal sling procedure. Since then, allograft fascia lata as well as autografts have been available. Other than the use of allografts beginning in August 1997 no selection criteria differed in the groups. After informed consent was obtained detailing the risks and benefits of the available procedures, patients selected the sling material. The allograft discussion included the potential risk of viral transmission with a theoretical risk of HIV transmission of 1/1,667,600 cases and unknown long-term durability.[9,13]

Fascial autografts were rectus fascia or fascia lata. The pubovaginal sling using rectus fascia was placed using the techniques described by Cross[5] and Chaikin[6] et al. The only difference in our technique was that autografts were 2 × 12 cm., folded and bound on each end with a long 2-zero nonabsorbable polypropylene suture. The autologous fascia lata sling procedure was done in a similar manner with the left thigh serving as the harvest site, permitting the use of a smaller 2 to 3 cm. suprapubic transverse incision instead of the customary Pfannenstiel incision. Exception for not harvesting fascia our allograft sling procedure was performed in identical manner fashion. Cadaveric fascia lata was obtained from 3 licensed regional tissue banks (81% from 1 source) using similar processing techniques, including freeze-drying and γ irradiation with a terminal dose of 15 to 25 kGy. Allografts were rehydrated in gentamicin impregnated 0.9% normal saline at room temperature for a minimum of 30 minutes before insertion.

The urethral catheter was removed on postoperative day 1. Urinary retention was managed by clean intermittent catheterization. If a suprapubic catheter had been inserted, a practice that was discontinued in November 1997, it was removed after a successful voiding trial, usually at the end of postoperative week 1. Followup pelvic examination was performed at 1 and 4 weeks, 3 and 6 months, and as needed thereafter.

For outcome analysis we reviewed the medical record to determine operative time, postoperative pain score and all complications. A third party telephone interview using our questionnaire was used to screen for urinary incontinence, and record postoperative pad use and patient satisfaction (see appendix). A detailed urogynecologic examination and videourodynamics were then performed if patients complained of stress, urge or mixed incontinence and were dissatisfied. Postoperative incontinence with 1 or more pads used daily was classified as recurrent stress urinary incontinence related to stress, persistent or new onset urge incontinence. These conditions were not mutually exclusive. Overall stress and urge incontinence outcomes were categorized by 24-hour pad use as cured—0, improved—1 and failed—more than 1 pad. Statistical analysis included the incidence, mean plus or minus standard deviation and range. We used 2-sample t, Fisher's exact chi-square and Fisher's exact tests when appropriate to examine the associations of sling material with outcomes with $p < 0.05$ considered significant.

RESULTS

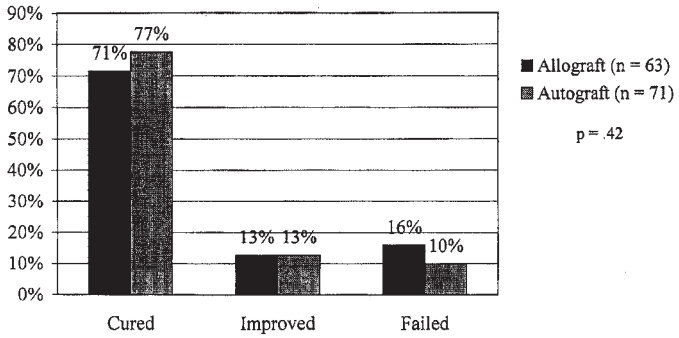
Our initial analysis of this cohort was done in 1999.[10] From this preliminary study 134 of 140 women were still available for evaluation in our continued analysis, including 63 with an allograft and 71 with an autograft (rectus fascia in 49 and fascia lata in 22). When the 2 grafts were available to patients, 63 of 74 (85%) elected an allograft. Preoperative parameters were similar in the 2 groups (table 1). Previous anti-incontinence surgery included a Marshall-Marchetti-Krantz procedure in 9 cases, Burch calposuspension in 7, Raz procedure in 6, Stamey needle suspension in 4, Kelly plication in 4 and a ProtoGen sling (Boston Scientific, Natick, Massachusetts) in 1. Mean followup plus or minus standard deviation was less in the allograft group (29 ± 3 versus 44 ± 7 months, $p < 0.05$). However, all patients were followed a minimum of 24 months. In our preliminary study mean followup was 8 months (range 3 to 15) in the allograft and 24 months (range 9 to 35) in the autograft group, which increased to 29 (range 24 to 36) and 44 months (30 to 56), respectively, in our current study.

There was no statistical difference in the overall stress and urge incontinence cure rate in the allograft and autograft groups (45 of 63 and 55 of 71 cases, see figure), nor was there a difference in the total number with recurrent stress urinary incontinence (8 and 7, respectively, table 2). In addition mean postoperative daily pad use was similar (0.7 ± 1.3 and 0.4 ± 0.8 pad, respectively). Most postoperative incontinence in the 2 groups was due to urge incontinence (table 2). Overall patient satisfaction was less in the allograft group (49 of 63 patients versus 64 of 71, $p = 0.05$). Using allografts instead of autografts resulted in significantly decreased operative time, postoperative pain, hospital stay and time lost from work (table 1). The site of autograft harvest (rectus abdominis or fascia lata) did not have a significant effect on postoperative pain or convalescence.

In the allograft group 18 of the 63 patients (29%) still required 1 or more pads daily, including 3 with recurrent

TABLE 1. *Comparison of preoperative patient characteristics, operative time, postoperative pain and convalescence*

No. Pts.	Allograft (63)	Autograft (71)	p Value (2 = sample t or Fisher's exact test)
Mean age (range)	54 (21–77)	53 (33–76)	0.65
Mean pads used/day ± SD	3.3 ± 2.2	3.8 ± 2.1	0.32
No. previous anti-incontinence surgery (%)	12 (19)	18 (25)	0.41
No. preop. urge incontinence (%)	38 (60)	32 (45)	0.09
No. stress urinary incontinence type (%):			
II	14 (22)	34 (48)	<0.05
III	20 (32)	15 (21)	0.17
II/III	29 (46)	22 (31)	0.08
Mean operative time ± SD (mins.)	69 ± 17	116 ± 23	<0.05
Mean postop. verbal numerical pain scale ± SD (range 0–10)[14]	2.0 ± 2.4	5.8 ± 2.0	<0.05
Mean hospital stay ± SD (days)	1.2 ± 0.4	1.9 ± 0.6	<0.05
Mean wks. lost from work ± SD	3.4 ± 2.2	6.4 ± 2.6	<0.05



Comparison of overall stress and urge incontinence cure, improvement and failure rates after allograft and autograft pubovaginal sling at minimum 2-year followup by Fisher's exact chi-square test.

stress urinary incontinence, 10 with urge incontinence, and 5 with stress urinary incontinence and urge incontinence. Stress urinary incontinence recurred in 8 cases, including less than 6 months and more than 2 years after surgery in 2 and 6, respectively. Recurrent stress urinary incontinence was due to persistent intrinsic sphincter deficiency with minimal or no hypermobility in all 8 patients. In this subgroup the average decrease in daily pad use was 1.8 while 2 of the 8 patients remained satisfied. Transurethral collagen injection was done initially for recurrent stress urinary incontinence in 3 patients, while 5 refused further therapy. A single injection achieved dryness in 1 patient, while 2 who received multiple injections without any significant improvement subsequently underwent autologous pubovaginal sling and became dry.

Similarly, in the autograft group 16 of the 71 patients (23%) still required 1 or more pads daily, including 5 with recurrent stress urinary incontinence, 9 with urge incontinence, and 2 with stress urinary incontinence and urge incontinence. Stress urinary incontinence recurred in 7 cases, including less than 12 months and more than 3 to 4 years after surgery in 1 and 6, respectively. Recurrent stress urinary incontinence was due to persistent intrinsic sphincter deficiency with minimal or no hypermobility in all 7 patients. In this subgroup the average decrease in daily pad use was 3.2 while 3 of the 7 patients remained satisfied. Transurethral collagen injection was done initially for recurrent stress urinary incontinence in 2 cases, while 5 refused further therapy. A single injection achieved dryness in 1 patient, while the other had no improvement after multiple injections.

Significant perioperative complications, such as hemorrhage requiring transfusion, death, ureteral injury, vaginal wound infection or urethral erosion, did not occur in either group. The 2 bladder perforations healed without consequences after 1 week of continuous bladder drainage. Infectious complications, such as urinary tract and abdominal wound infection were greater in the autograft than in the allograft group (19 and 4 cases versus 4 and 0, respectively). This result was attributable to routine suprapubic cystotomy tube placement in the autograft group before 1997. Pelvic prolapse did not develop during routine postoperative 0 through 6-month followup. Of the patients who were examined beyond this period for reported urinary incontinence only 1 with prolapse was noted in either group, involving a large cystocele associated with mixed incontinence after an autograft sling. Urinary retention beyond 30 days was rare in each group. Prolonged retention resolved spontaneously in 1 of 1 case in the allograft group after 56 days compared within 2 of 3 in the autograft group (1 after 45 and 1 after 90 days), while 1 of 3 patients in the autograft group required transvaginal urethrolysis 1 week after surgery for urethral obstruction on physical examination. The patient began to void 1 week after urethrolysis and remained continent.

DISCUSSION

The periodic change in sling material is intended to simplify the procedure, making it more reproducible while decreasing morbidity. Current alternatives to autografts include synthetic and allogenic materials, although each has distinct drawbacks. Synthetic slings are effective for curing stress urinary incontinence but an unacceptable incidence of local complications, such as urethral and/or vaginal erosion, requiring sling removal has decreased their use 1% to 23%.[1,15] Nevertheless, the early success of tension-free vaginal tape, which is composed of polypropylene mesh enclosed in a plastic sheath, has generated renewed interest.[16] Conversely allograft slings avoid urethral and vaginal complications but have unknown long-term durability.[8,9] In addition, the transplantation of any allograft causes a risk of viral transmission.

The risk of viral transmission after placing soft tissue allografts is almost eliminated by combining donor screening and testing with a multistep sterilization processes before use.[8,9,17] In fact, the risk of acquiring HIV from a properly screened but infected donor of 1/1,667,600 to 1/8,000,000 is significantly less than the 1/440,000 to 1/600,000 risk of acquiring HIV infection from blood transfusion.[9,13,17,18] Nevertheless, the potential risk of transmission of other infectious agents, such as prions, may still exist.[17,19] Although the sterilization process effectively eliminates viruses from the allograft, it may potentially compromise its future stability.

In 1996 Handa et al first reported the use of allograft fascia lata for a pubovaginal sling as an alternative graft that would avoid the morbidity of fascial harvest.[8] Although this application is relatively new, extensive evidence in the orthopedic and opthalmological literature supports the safety and long-term stability of allografts in reconstructive surgery.[8,9,17,20] However, the success of allografts in other specialties may not necessarily translate into successful pubovaginal sling surgery. Difficulty in projecting success exists because of wide variations in allograft type, thickness, length and processing.

Preliminary reports show that using allografts for a pubovaginal sling can result in significantly decreased operative time and hospital stay without compromising efficacy at less than 1 year (79% to 98%) or safety.[8,9] We reported similar results in our initial review and also objectively identified a significant 83% decrease in median postoperative pain using a nonvisual analog scale as well as a significant 50% decrease in the median time to normal activity.[10] Despite these early successes there continues to be uncertainty about the usefulness of allografts for pelvic reconstructive surgery. Skepticism is due to reports of a 20% early failure rate of allograft pubovaginal slings[11] and 38% for transvaginal slings with bone anchors.[12] Fitzgerald[11] and Carbone[12] et al attributed these disappointing results to cadaveric fascia and, therefore, abandoned its use.

In response to this controversy we evaluated the pubovaginal sling outcome in our patients with a minimum 2-year followup. We compared our continued experience with the same cohort of patients in our initial report who underwent an allograft or autograft pubovaginal sling procedure. There was no statistical difference in overall (71% and 77%) or stress urinary incontinence cure (87% and 90%) cure in the allograft and autograft groups, respectively. It is generally accepted that most sling failures due to recurrent stress urinary incontinence occur within year 1.[5] However, there were only a few failures in our review in either group during year 1. The majority of failures presented 2 to 3 years after the pubovaginal sling procedure. The significant increase in recurrent stress urinary incontinence in the 20-month period between reviews was similar in the allograft and autograft groups (10% and 9%, respectively, $p = 0.76$, table 2). Similarly, Amundsen et al recently reported a 16% incidence of

TABLE 2. *Comparison of incontinence outcomes after allograft and autograft pubovaginal sling in preliminary and current reports*

	No. Pts./Total No. (%)		p Value (Fisher's exact test)
	Allograft	Autograft	
Preliminary data:[10]			
Recurrent stress urinary incontinence	2/63 (3)	1/71 (1)	0.46
Urge incontinence	6/63 (10)	7/71 (10)	0.84
Persistent urge incontinence	5/38 (13)	6/32 (19)	0.50
New onset urge incontinence	1/25 (4)	1/39 (3)	0.53
Current data:			
Recurrent stress urinary incontinence	8/63 (13)	7/71 (10)	0.58
Urge incontinence	15/63 (24)	11/71 (16)	0.23
Persistent urge incontinence	8/38 (21)	9/32 (28)	0.48
New onset urge incontinence	7/25 (28)	2/39 (5)	<0.05

recurrent stress urinary incontinence in patients with a freeze-dried nonirradiated allograft pubovaginal sling at 19.4 months, which is more than the 2% in their initial report (table 3).[9, 19] A summary of contemporary pubovaginal sling results shows that our mean followup and overall cure rate in each group are similar to respective allograft and autograft pubovaginal sling outcomes (table 3).[5, 6, 17, 21, 22]

We observed a disturbing incidence of postoperative urge incontinence in each group that increased with time. This finding explained most overall failures and was the primary cause of patient dissatisfaction. This disturbing trend was also reported in other allograft as well as autograft pubovaginal sling studies (table 3).[6, 19] It is unknown whether urge incontinence after pubovaginal sling placement was related to prolonged bladder outlet obstruction or to an aging detrusor.

The successful allograft pubovaginal sling outcome in our review and in other reports was achieved using fascia lata slings that were at least 12 cm. long and without bone anchors (table 3).[9, 17, 19, 22] In contrast, the disappointing allograft transvaginal sling results of Carbone et al involved a 7 cm. strip of cadaveric fascia that was transfixed with bone anchors.[12] Therefore, differences in sling length and the fixation technique may have explained the conflicting outcomes. However, Fitzgerald et al used a 10 cm. strip of freeze-dried γ irradiated cadaveric fascia without bone anchors and noted an early failure rate of 20%.[11] Therefore, other factors, such as outcome measures, allograft thickness and proprietary differences in manufacturer processing and storage techniques, may explain dissimilar results. Furthermore, differences in patient demographics, estrogen status and concomitant pelvic surgery can be confounding variables. Biomechanical analysis designed to eliminate or control these factors has also shown conflicting results.[19]

In 1997 clinical guidelines were established for the surgical management of stress urinary incontinence.[1] A shortcoming noted in this analysis was the wide variability in how groups defined cure, ranging from completely dry to improved. Whether cure refers to absent stress and urge incontinence or just stress urinary incontinence was not always apparent. In addition, the long-term cure rate often includes recent results at 1 to 24 months. Furthermore, it is often difficult to contact patients who participated in a preliminary study for subsequent reviews. To avoid these problems we used our autograft data for comparison as well as identical outcome measures. We excluded all patients who received a pubovaginal sling in the last 2 years and contacted 96% of those in our initial analysis. Using these guidelines we did not observe any difference in efficacy for the allograft and autograft pubovaginal slings at 2 years.

A drawback of our study was the difference in followup in the 2 groups, which may have created a lead-time bias for detecting recurrent stress urinary incontinence. Another issue is that allografts were obtained from 3 tissue banks due to the allograft shortage when we began to use this material. Although we attempted to minimize these drawbacks, only a prospective randomized trial would avert all of these impediments. Nevertheless, due to individual reservations concerning cadaveric tissue not all patients may agree to randomization.

The goals of improving any standard surgical procedure or creating a completely new operation customarily involve alterations in technique that would create a less complex procedure with decreased morbidity. These modified or new procedures initially create enthusiasm, although with time they often lose favor due to unanticipated complications or lack of durability. An example is the ProteGen sling (Boston Scientific, Natick, Massachusetts), which was withdrawn by the manufacturer due to an unacceptable incidence of urethral-vaginal erosion as late as 7 years after implantation.[15] Recently tension-free vaginal tape has created tremendous interest after Ulmsten et al reported an 86% cure rate with no vaginal complications at 3 years.[16] However, in addition to bladder or urethral injuries that can occur in many anti-incontinence procedures, there are also unique complications of tension-free vaginal tape, such as external

TABLE 3. *Contemporary allograft and autograft pubovaginal sling outcomes*

References	Sling Type	No. Evaluable Pts.	Mean Mos. Followup (range)	No. Cure (%)*		No. Persistent + New Onset Urge Incontinence (%)*
				Overall	Stress Urinary Incontinence	
Beck et al[21]	Autograft fascia lata	170	25 (1–120)	157 (92)	167 (98)	10 (6)
Cross et al[5]	Autograft rectus fascia	134	22 (6–42)	121 (90)	124 (93)	38 (28)
Chaikin et al[6]	Autograft rectus fascia	251	37 (12–180)	183 (73)	237 (94)	45 (18)
Elliot and Boone[22]	Allograft fascia lata	26	15 (12–20)	20 (77)		11 (42)
Brown and Govier[17]	Allograft fascia lata, autograft fascia lata	104, 30	12, 44	77 (74), 22 (73)	88 (85), 27 (90)	
Wright et al[9]	Allograft fascia lata, autograft rectus fascia-fascia lata	59, 33	10 (1–20), 16 (15–28)		58 (98), 31 (94)	15 (25), 7 (21)
Amundsen et al[19]	Allograft fascia lata	91	19 (3–37)	68 (75)	76 (84)	49 (54)
Present series	Allograft fascia lata, autograft rectus fascia-fascia lata	63, 71	29 (24–36), 44 (30–56)	45 (71), 55 (77)	55 (87), 64 (90)	15 (24), 11 (16)

* Definitions varied widely among series. For example, Amundsen et al included patients who reported an occasional episode of urge incontinence,[19] while we counted only those using 1 or more pads daily.

iliac vein perforation by the trocar used to insert the tape.[23] Therefore, changes in sling material or surgical technique from the gold standard autograft pubovaginal sling should proceed judiciously until long-term data are available and reproducible by multiple groups.

CONCLUSIONS

Using allograft fascia lata as an alternative to autograft fascia for a pubovaginal sling results in a minimally invasive ambulatory procedure for stress urinary incontinence due to a significant decrease in postoperative pain and disability. In addition, using allograft fascia for the pubovaginal sling continues to provide efficacy comparable to that of autograft fascia at 2 years. Therefore, we believe that allograft fascia should remain a suitable alternative to autografts when performing the pubovaginal sling procedure.

APPENDIX: QUESTIONNAIRE

1. Do you leak urine when you cough, strain or during physical activity?
2. Do you have any urgency to void? Meaning, once you need to urinate, do you leak urine if you do not do so immediately? If yes, are you being treated with medication, biofeedback or other devices for this problem?
3. Do you wear a pad because of leakage? If yes, how many?
4. If your incontinence returned after surgery, when did this first occur?
5. Have you had any additional procedures performed for leakage (i. e. transurethral collagen injection, repeat pubovaginal sling)?
6. Have you noticed any bulge in your vagina since the surgery?
7. Knowing what you know now, if you were able to make the decision over again about having sling surgery, would you make the same choice?
8. Would you recommend sling surgery to a friend with a similar incontinence problem?
9. How long after the surgery was it before you were capable of resuming full activity?

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